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[English summary]

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#### CLAIMS

1. The electric heart pacemaker is distinguished by its circuit with provisions for automatic control of the pacemaker's impulse frequency through deep body temperature as the manipulated variable, preferably through the temperature of the central blood of the heart.
2. As described under Claim #1, the heart pacemaker is distinguished by an electric temperature sensor (6) which can be placed in a chamber of the heart (4) of the patient (8). The sensor is connected across leads (7a and 7b) in such a manner that the stimulation frequency is automatically controlled as a function of the deep body temperature, especially of the central blood temperature.
3. As under Claim #2, the heart pacemaker is distinguished by the installation of an electric temperature sensor in the tip of the heart catheter (9), at which at least the excitation electrode (3a) for application of the pacemaker impulse is located. The sensor is connected with the electric impulse inducer (2) across the control lead (7a, 7b) laid in the catheter tube (9) (Figure 3).

4. As under Claims #1 to #3, the heart pacemaker is distinguished by combination of one lead-in (7a') for the temperature sensor (6) with and electrode lead-in, preferably with the lead-in (5b) for the indifferent application electrode (3b) of the pacemaker.
5. As under one of Claims #1 to #4, the heart pacemaker is distinguished by use of one of the following electric components as the temperature sensor: passive temperature-discriminating elements, such as high-temperature conductors (thermistors), conductors with a negative temperature coefficient, diodes, transistors, and active temperature-discriminating elements, such as thermocouples.
6. As under one of Claims #1 to #5, the heart pacemaker in combination with unipolar or bipolar, endocardiac or epicardiac, and intramural electrode catheters.
7. As under one of Claims #1 to #6, the heart pacemaker with extracorporeal or implantable arrangement of the impulse timer and the voltage supply source.
8. As under one of Claims #1 to #7, the heart pacemaker is distinguished by use of and/or combination with excitation that is independent of heart frequency and/or fixed frequency excitation of the pacemaker impulses.
9. As under one of Claims #1 to #8, the heart pacemaker is distinguished by a transistorized blocking oscillator as impulse inducer. Its control electrode (11a) is connected with the temperature sensor (6) across the control lead (7a, 7b) preferably in a manner that the temperature-discriminating sensor (6) forms the basis resistance of one of the oscillating transistors (11, 12) (Figure 4).

Dr. of Medicine Georg Csapo

Freiburg im Breisgau, February 13, 1976

Application for Patent and Registered DesignElectric Heart Pacemaker

The subject of the submitted invention is an electric heart pacemaker. The repetition frequency of its excitation impulse is automatically controlled in dependence on the body temperature and/or the central blood temperature. The invention's original characteristics are distinguished in making the claims.

Since the first successful electric stimulation of the human heart more than 70 years ago (Zoll, P.M. [etc.]), the electric heart pacemaker has become an indispensable aid in treating disturbances due to excitement formation and especially spread of excitement. Today, most difficulties initially connected with implantation of heart pacemakers are considered resolved, so that for many years now reliable, functionable heart pacemakers of small dimensions, of light weight, and with extensive physiological compatibility have been available to the doctor for the stimulation of heart activity. The standard conditions for the various requirements of therapy have been extensively established, namely, in regard to the frequency, the form, and the breadth of pacemaker impulses, as well as in regard to the triggering characteristics. There is the possibility of a fixed frequency excitation (stimulation) of the heart or of an auricle-triggered stimulation. Finally, there is available also what is known as QRS-inhibiting pacemakers, or demand-pacemakers. With these, stimulation is controlled with an intracardiac electrode probe by automatically suppressing the pacemaker's impulses for as long as an electrical spontaneity of the chambers takes place. If, however, the natural excitation of the heart ceases for a definite given time, pacemaker impulses are supplied, predominantly fixed frequency impulses with approximately 70 beats per minute. By using the other type, namely, stimulation

controlled by natural heart actions, first of all, energy consumption of the pacemaker is reduced, which is especially important with implanted pacemakers; secondly, unnecessary and even harmful irritation of the heart from interference with natural actions is avoided.

Of the pacemakers used for long-range therapy today, the overwhelming majority has the disadvantage that the stimulation frequency must be fixed prior to implantation, so that a rise in the heart minute volume can only be achieved by means of an increase in the heartbeat volume. However, this is inadequate with medium to heavy physical exertion, and especially so with ethylic myocardia. It can impair the capacity for activity of the pacemaker wearer considerably.

When the heart is healthy, the heart frequency required for peak efficiency of the heart-circulatory system is produced by the sinus node. When treatment of heart disturbance by means of the electric heart pacemaker does not involve taking the electric impulse induced by the natural sinus node from the auricle in the chamber region of the heart, the first step would be to control the stimulation frequency of the artificial pacemaker through the impulses of the sinus node. Such pacemakers, known as pulmonary-wave (P-wave) controlled heart pacemakers, are available and were implanted as early as 1962 by Nathan, Center, and colleagues (Nathan, D.A., [etc.]). The practical disadvantages of pacemaker systems that are controlled by the P-wave have to date not been overcome, however, so that only a fraction of implanted pacemakers are of this type. Their basic fault is that the electric voltage of the P-wave has to be taken from a separate electrode, anchored in the auricle region, and led to the pacemaker. Anchoring of such an auricle electrode in the auricle is not reliably possible by insertion of a catheter through a vein, however (Büchner, Ch., Dräger, W.: [etc., title rendered in English read: Pacemaker

Therapy of the Heart, etc.])). Fixing of an auricle electrode is reliably possible only with operative intervention by opening of the thorax and with the obvious disadvantages and risks connected with this method.

Disadvantages of P-wave controlled pacemakers have caused a search for other possibilities for frequency control of the pacemaker in dependence on work load. For example, H. D. Funke has suggested automatic variation of the pacemaker impulse frequency in dependence on breathing frequency (H.D. Funke; [etc., English rendering of title: A Heart Pacemaker with Frequency Regulation in Dependence on Work Load. etc.])). With this, however, it is first of all a disadvantage that breathing can be influenced by will; and secondly, that reliable inclusion of breathing activity involves considerable expense.

The submitted invention is based on the knowledge that it would be physiologically very advantageous to adapt the frequency of stimulation by pacemakers and thereby heart frequency to the physical work load of the pacemaker wearer. The aim of the invention is to achieve this through the deep body temperature, and preferably through using the central blood temperature as the manipulated variable for control of the pacemaker impulse frequency. Measurements of the intracardiac blood temperature by the inventor have confirmed the known fact of dependence of central blood temperature on physical work load. For example, using a bicycle ergometer, an increase of the central blood temperature by approximately  $1^{\circ}\text{C}$  was established when the work load on the patient was 125 watts. In view of this, the excitation-impulse frequency ought to be regulated automatically as a function of deep body temperature, generally in the same direction, while a linear dependence in separate areas is not to be excluded. But the frequency change will mainly be less steep with a higher blood tem-

perature than with a lower temperature. For example, with a temperature interval of 37° to 39°C there could be a frequency interval of 70 to 100 impulses, a maximum of 110 impulses per minute.

The physiological significance of the invention lies especially in the fact that with higher temperature there is also a greater need for oxygen in the heart and body, which can only be met by an increase in blood flow and therefore by raising of the heartbeat frequency. In fact, there are already pacemakers, and even fixed frequency as well as demand devices, with which excitation intensity and frequency can be adapted to certain physiological conditions when present. This adaptation, however, has always had to take place by manual operation at each occurrence, and a choice of more than two or three frequency values has not been available. In contrast, the conception of the invention foresees an automatic, preferably continuous control of stimulation frequency in functional dependence on the blood temperature.

Drawings are cited in the description below.

Diagram 1 illustrates with a circuit sketch the basic principle of the invention. Diagram 2 serves for illustration of an application possibility of a heart pacemaker. Diagram 3 shows a possible form of installation of the tip of a stimulation catheter. Diagram 4 presents the circuit sketch of a pacemaker using the principle of a blocking oscillator, with the provisions that distinguish the invention.

For a more detailed description of the invention's concept, battery-powered pacemakers are assumed as the model. These are presently seen as the ideal form for the pacemaker, and they do guarantee disturbance-free stimulation for at least several weeks. The patient is unencumbered and free to move. Such a pacemaker contains as its main part the electric impulse inducer (2), the voltage supply battery (1); both of which are usually enclosed in a capsule (10) (see diagram 2), and also contained

are the lead-ins 5a and 5b for the stimulation electrodes 3a and 3b, which are implaced in or at the heart (4). For realizing the invention's concept, provision for an electric temperature sensor (6) is made, which can be laid eventually in a chamber of the heart. The sensor is connected across the electric leads 7a and 7b with the impulse inducer (2) of the pacemaker in such a manner that the stimulation frequency is automatically controlled in the same direction as temperature variations in the heart.

In principle, control of stimulation frequency can be applied with endocardiac or epicardiac, with unipolar or bipolar, and, finally, with an intramural type of excitation of the heart. Their electrodes and their lead-ins, which preferably are laid in catheter tubes, should be designed to correspond to these possibilities. It should be noted that the design of the application electrodes and their lead-ins, as well as their implacement or application in the heart, pose the main technological difficulties with artificial heart excitation, rather than the electronic part. In particular, constant movement, due to the heartbeats, of the electrodes and their lead-ins requires highly flexible materials, and in fact, not only in the lead cables and electrodes, but also in the insulation tubes. Nevertheless, these problems can be viewed as solved for the most part, but they are not the subject of the submitted invention.

Automatic control of the impulse frequency of the pacemaker, as foreseen in the conception of the invention, is also applicable — whether a fixed frequency stimulation is intended and the impulse inducer is arranged accordingly, or whether the artificial stimulation is to be engaged only as needed (demand principle). In contrast, the conception of the invention does not apply to pacemakers known as auricle-controlled heart pacemakers, for which impulses of the heart action, and in fact of the P-wave of the auricle, are triggered synchronically. For the latter, a special sensor for the natural heart action is thus required, one with

appropriate lead-ins to the impulse inducer, so that these trigger when a certain phase of the heart action occurs (mainly occurrence of the P-wave).

The provisions of the invention can eventually be applied with extracorporeal arrangement of the pacemaker or with pacemakers (10) that are implanted in the body of the patient (8). With bipolar stimulation, two small-faced electrodes of equal size, located closely to one another, are brought into contact with the myocard. With unipolar stimulation, the excitation electrode itself is in contrast small-faced and is preferably anchored in the inner wrapping of the heart chamber, as diagram 2 shows, while the indifferent opposite electrode 3b is supposed to be broad-faced and can be attached to anyplace on the heart, preferably on its outer wrapping. The excitation electrode 3a itself should be connected with the minus pole of the battery (negative), because in this way the tissue irritation at the excitation point is especially mild and only a minimum of impulse voltage is required.

Diagram 3 shows the conception of the invention in the case of a bipolar intercardiac electrode. In this case, the excitation electrode 3a is located at the tip of an intracardiac catheter (9), a tube made of insulation material, while the indifferent electrode 3b is located some distance behind. Its lead-in cables 5a and 5b are laid in the inside of the catheter tube (9). It is a distinct feature of the invention that the arrangement of a temperature sensor (6) is likewise at the tip of the catheter—for example, between the two electrodes. The sensor's lead-ins 7a and 7b are also laid in the catheter tube. With this, however, one lead-in 7a could combine by a particular electronic control circuit with the lead-in 5b for the indifferent electrode 3b.

Passive or active temperature-discriminating elements can be used



as the temperature sensor — thus, high-temperature conductors (thermistors), conductors with a negative temperature coefficient, diodes, transistors or thermocouples.

Their purpose is to control the impulse frequency of the impulse inducer (2) in dependence on the temperature of the environment. With a type of performance conforming to the blocking oscillator principle of pacemakers based on the circuit sketched in diagram 4, the temperature sensor functions as the base resistor in the base circuit of one transistor (11) of the blocking oscillator. The bias voltage is thereby changed with the temperature; the frequency of the blocking oscillator is controlled across transistors (11) and (12). Frequency control is achieved in a similar manner when using multivibrators as impulse-inducing elements.

The frequency of the stimulator is mainly controlled in the same direction with temperature; that is, the frequency of the excitation impulse should rise with a rise in temperature. And, in fact, in general a temperature interval between 37°C and 39°C should correspond to a frequency interval of 70 impulses per minute up to 110 per minute.

Pacemakers with an automatic control of pacemaker frequency in dependence on temperature, as conforms to the invention's concept, meet physiological requirements better and more functionally than the forms of pacemakers to date that do not have continuous frequency adaptation. However, with pacemakers conforming to the invention, the advantageous characteristic is also kept, which is that only a single catheter which also contains the temperature sensor, needs to be inserted along the vein as in the usual method of pacemaker implantation to date. In addition, it is an advantage that many disturbances in the pacemaker system can be discovered whenever the pacemaker frequency no longer follows the variations in the temperature of the environment in the prescribed way,

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especially with temperature rises that are unphysiologically quick.  
Thus, the temperature-controlled frequency variation can also be used  
as a monitor of functions of the pacemaker system.